Exhibit I

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IN THE UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

[UNDER SEAL]

Relator,

v.

[UNDER SEAL]

Defendant.

Case No. 2:09-CV-0279 WBX EFB

FIRST AMENDED COMPLAINT AND JURY TRIAL DEMAND

FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. § 3730

DO NOT ENTER INTO PACER

DO NOT PLACE IN PRESS BOX

UNITED STATES OF AMERICA ex rel. Adolfo Schroeder, Relator,

STATE OF ARKANSAS ex rel. Adolfo Schroeder, Relator,

STATE OF CALIFORNIA ex rel. Adolfo Schroeder, Relator,

STATE OF DELAWARE ex rel. Adolfo Schroeder, Relator,

DISTRICT OF COLUMBIA ex rel. Adolfo Schroeder, Relator,

STATE OF FLORIDA ex rel. Adolfo Schroeder, Relator,

STATE OF GEORGIA ex rel. Adolfo Schroeder, Relator,

STATE OF HAWAII ex rel. Adolfo Schroeder, Relator,

STATE OF ILLINOIS ex rel. Adolfo Schroeder, Relator,

STATE OF INDIANA ex rel. Adolfo Schroeder, Relator,

STATE OF LOUISIANA ex rel. Adolfo Schroeder, Relator,

STATE OF MASSACHUSETTS ex rel. Adolfo Schroeder, Relator,

STATE OF MICHIGAN ex rel. Adolfo Schroeder, Relator,

STATE OF MONTANA ex rel. Adolfo Schroeder, Relator,

STATE OF NEVADA ex rel. Adolfo Schroeder, Relator,

STATE OF NEW HAMPSHIRE ex rel. Adolfo Schroeder, Relator,

STATE OF NEW JERSEY ex rel. Adolfo Schroeder, Relator,

STATE OF NEW MEXICO ex rel. Adolfo Schroeder, Relator,

§

Civil Action No. _____

FIRST AMENDED COMPLAINT AND JURY TRIAL DEMAND

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STATE OF NEW YORK ex rel. Adolfo Schroeder, Relator,

STATE OF OKLAHOMA ex rel. Adolfo Schroeder, Relator,

STATE OF RHODE ISLAND ex rel. Adolfo Schroeder, Relator,

STATE OF TENNESSEE ex rel. Adolfo Schroeder, Relator,

STATE OF TEXAS ex rel. Adolfo Schroeder, Relator,

STATE OF VIRGINIA ex rel. Adolfo Schroeder, Relator,

STATE OF WISCONSIN ex rel. Adolfo Schroeder, Relator,

vs.

MEDTRONIC INC.

Defendants.

COMPLAINT FOR DAMAGES UNDER THE FEDERAL FALSE CLAIMS ACT AND VARIOUS STATE FALSE CLAIMS ACTS AND DEMAND FOR JURY TRIAL

I. INTRODUCTION

1. Medtronic Inc. ("Medtronic") is a medical technology company that manufactures healthcare products. Medtronic's business areas include Cardiac Rhythm Disease Management ("CRDM"), Spinal and Biologics, CardioVascular, Neuromodulation, Diabetes, and Surgical Technologies. Within its CRDM business, Medtronic produces and markets pacemakers to treat patients with bradycardia (too-slow heartbeat), implantable defibrillators to help patients with tachyarrhythmia (too-fast heartbeat), and diagnostic and monitoring devices that diagnose heart-related syncope (unexplained fainting), among other products. Medtronic also makes the leads that connect these devices to the heart. The Food

and Drug Administration ("FDA") has approved these devices for use in monitoring and correcting heart rates that are out of rhythm.

2. In order to increase sales of their CRDM devices, Medtronic has illegally provided monetary and other incentives for physicians who were willing to implant the devices. Medtronic trained and instructed sales representatives, business and marketing managers, and other executives to offer physicians cash payments, expensive trips and meals, expensive gifts, and entertainment to physicians as kickbacks in exchange for the physicians' agreement to implant Medtronic devices.

3. Medtronic also promoted non-FDA-approved, or "off-label" use of CRDM devices. Medtronic funneled millions of dollars in unrestricted grant money to physicians in order to encourage them to speak and publish articles supporting the use of Medtronic CRDM products in asymptomatic patients and patients whose mild heart failure symptoms did not meet the FDA criteria for an implantable device. Specifically, Medtronic targeted, developed, and trained physician "Key Opinion Leaders" ("KOL"s), influential doctors whom Medtronic supported monetarily. Medtronic, in turn, expected these KOLs to support Medtronic device use among asymptomatic patients and patients with only mild symptoms of heart failure. Medtronic then pointed to the KOLs' use of CRDM devices when promoting the devices widely among other cardiologists and electrophysiologists throughout the country.

4. Consistent with its scheme to provide illegal incentives to doctors who implanted its devices, Medtronic also gave kickbacks to physicians for off-label use of the devices, providing the physicians with speaking opportunities, unrestricted educational grants, travel, lavish meals, gifts of wine and alcohol, trips to strip clubs, and honoraria to promote and implant Medtronic CRDM devices off-label. Paid travel included trips to San Francisco, Las Vegas, New Orleans, New York, Atlanta, Chicago, San Diego, Minneapolis, and other locations. At these "fly-to"

events doctors would sometimes come just for vacation, and would not attend the majority of the "educational" seminars offered by Medtronic. Medtronic knew that many physicians viewed Medtronic's paid travel offers as simply a free vacation, but continued to encourage the physicians' attendance as a form of quid pro quo for increased sales of CRDM devices.

5. Medtronic's efforts to promote implantable cardioverter-defibrillators ("ICD"s) for use in people who do not need the devices has been damaging to the government and to patients, because their diagnosis, treatment, and implants were unnecessary. At least one study has revealed that more than 75% of ICD devices never deliver any shock at all—in other words, there is little or no benefit from these devices, for which federal and state governments have paid the bill. For example, a January 20, 2005 study published in the New England Journal of Medicine found that only 21.35% of 829 patients implanted with an ICD received a therapeutic shock for the indicated heart failure problem (*See* Dr. Gust H. Bardy, et al, "Amiodarone or an Implantable Cardioverter-Defibrillator for Congestive Heart Failure," The New England Journal of Medicine, Jan. 20, 2005, attached hereto as Exhibit 1).

6. Medtronic's scheme to promote the broad off-label use of Medtronic's CRDM devices among asymptomatic and mildly symptomatic patients and to influence studies promoting Medtronic's CRDM devices for use in such patients is dangerous. A 2008 study published in The New England Journal of Medicine noted that 17.4% of persons with a Medtronic implantable cardio-defibrillator (ICD) received an inappropriate shock, and that for all shocked patients, there was a significant increase in the rate of death due to progressive heart failure compared to patients who received no shock. The study found that 10.73% of the patients received only inappropriate shocks from the devices, and that inappropriate ICD shocks nearly doubled the risk of death in implantees (*See* Dr. Jeanne E. Poole, et al, "Prognostic Importance of Defibrillator Shocks in Patients with Heart Failure,"

The New England Journal of Medicine, Sep. 4, 2008, attached hereto as Exhibit 2). An April 8, 2008 review of 719 patients in the MADIT II study of ICD devices found that 11.5% of implantees received an inappropriate shock, causing increased risk of death from all causes. (*See* Dr. James P. Daubert, *et al.*, "Inappropriate Implantable Cardioverter-Defirillator Shocks in MADIT II," Journal of the American College of Cardiology, April 8, 2008, attached hereto as Exhibit 3). Medtronic's scheme to promote CRDM devices for off-label use in mildly symptomatic and asymptomatic heart failure patients was thus both illegal and dangerous.

7. Additionally, Medtronic's CRDM devices were not superior to other similar devices made by other companies on the market. As described in this Complaint, Medtronic's scheme to promote the devices for off-label use, and to pay kickbacks and give gifts to physicians who would agree to use Medtronic devices resulted in financial damage to state and federal health care systems.

8. Federal laws and regulations governing Medicaid and Medicare and similar state statutes prohibit medical device manufacturers from providing kickbacks to physicians and medical care providers. Specifically, the federal healthcare program anti-kickback provision, 42 U.S.C. § 1320a-7b(b) (2)(B), provides:

> [W]hoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person . . . to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

9. The Medicare and Medicaid anti-kickback laws, 42 U.S.C. 1320a-7b(b), *et seq.*, regulate drug and device marketing in order to prevent over-utilization of medical care, medication, and medical devices. Under the anti-

kickback laws, companies may not offer or pay any remuneration, in cash or kind, to induce physicians or others to order or recommend drugs or devices which may be paid for by a federal healthcare program such as Medicare or Medicaid. These regulations not only prohibit outright bribes and rebate schemes, but prohibit any payment, remuneration, gratuities, and other benefits paid by a company to a physician which has as one of its purposes inducing the physician to use the company's products.

10. In addition to the anti-kickback laws, §1877 of the Social Security Act, often referred to as the "Stark law," provides that a physician cannot (1) refer patients to an entity (2) for the furnishing of DHS (designated health services) (3) if there is a direct or indirect financial relationship between the referring physician (or an immediate family member of the referring physician) and the entity, (4) unless the financial relationship fits within one of the specific exceptions in the statute or regulations. *See* 42 U.S.C. §1395nn. For purposes of the Stark law, DHS includes durable medical equipment and supplies. Unlike the Medicare Anti-Kickback Statute, which is a criminal statute requiring at least some measure of criminal intent, the Stark Statute is a civil statute requiring strict compliance. Intent to violate or substantial compliance has no bearing on whether an activity is or is not legal. Violation, no matter how unintentional or technical, is sufficient to invoke the Stark Statute. Lastly, if a prohibited referral occurs under Stark, the DHS entity may not file or cause to be filed a claim under Medicare or Medicaid or a bill to any individual, third party payer, or other entity for the designated health services provided.

11. Had the United States and the several States known that CRDM devices were being used by facilities because physicians in those facilities had accepted kickbacks from Medtronic, the United States and the several States would not have funded these illegal kickbacks after the fact by providing reimbursement for Medtronic devices.

12. Moreover, the kickbacks described in this Complaint are strictly illegal and have had the direct effect of greatly increasing the amount of CRDM devices that have been paid for and reimbursed by the government. Accordingly, the kickbacks have had the indirect effect of increasing the amount of money spent by the federal government and the States for payments and reimbursements covered by Medicaid, Medicare, and the TRICARE health care system for members of the military and their families. Medtronic's kickbacks to physicians represents the inducement of payment from the government through a pattern of fraudulent conduct, constituting false claims within the meaning of 31 U.S.C. § 3729 and the relevant provisions of the state false claims and state and federal healthcare system fraud statutes.

II. PARTIES

13. Relator Aldolfo Schroeder has worked in pharmaceutical and medical device sales since February 1996, and started at Medtronic in May 2006. At Medtronic, Mr. Schroeder was a Business Development Manager who promoted CRDM devices. Mr. Schroeder participated in regular company training events, including events at Medtronic's headquarters in Minneapolis. He also attended national and regional sales training conferences, where he interacted with various company marketing executives and managers. Mr. Schroeder left Medtronic in July 2007 and now works for CardioNet promoting Mobile Cardiac Outpatient Telemetry devices. While at Medtronic, Mr. Schroeder developed first-hand knowledge of the facts set forth in this Complaint. Mr. Schroeder is therefore an original source of the facts and information set forth in this Complaint concerning the activities of Medtronic.

14. The facts averred in this Complaint are based entirely upon the personal observations of Mr. Schroeder and documents in his possession.

15. Mr. Schroeder has provided or is providing to the United States Attorney and the Attorneys General of Arkansas, California, Delaware, Florida,

Georgia, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Michigan, Montana, New Hampshire, New Jersey, New Mexico, New York, Nevada, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Wisconsin and the District of Columbia a full disclosure of substantially all material facts supporting this Complaint, as required by the False Claims Act, 31 U.S.C. § 3730(b)(2), and relevant state statutes.

16. Defendant Medtronic is incorporated in the United States in the State of Minnesota. Medtronic has its world corporate headquarters in Minneapolis, Minnesota. Medtronic is principally engaged in the manufacture and sale of healthcare technology products including pacemakers, implantable cardioverter defibrillators, and cardiac resynchronization therapy defibrillators falling under the jurisdiction and regulation of the U.S. Food and Drug Administration. Devices manufactured and marketed by Medtronic include the Concerto CRT-D (cardiac resynchronization therapy and defibrillator) and Virtuoso DR ICD (implantable cardioverter defibrillator); the InSync Sentry CRT-D, the OptiVol fluid status monitoring device; CardioSight and Cardiac Compass cardiac monitoring devices; Reveal insertable loop recorder; sprint-fidelis lead system and other lead systems; cardiac compass monitoring device; carelink monitoring wireless at home system; and any additional ICD, CRT, pacemaker, fluid monitoring, cardiac monitoring devices, processes and lead systems sold by Medtronic from 2002 to present.

III. JURISDICTION AND VENUE

17. This action arises under the False Claims Act, 31 U.S.C. §§ 3729 *et seq.* This Court has jurisdiction over this case pursuant to 31 U.S.C. §§ 3732(a) and 3730(b). This court also has jurisdiction pursuant to 28 U.S.C. § 1345 and 28 U.S.C. § 1331. This court has jurisdiction over the state law counts asserted in this Complaint under both 31 U.S.C. § 3732(b) and 28 U.S.C. § 1367, because the state claims arise from the same transaction or occurrence as the federal claims and because these claims are so related to the federal claims that they form part of the same case or controversy under Article III of the U.S. Constitution.

18. At all times material to this Complaint, Medtronic regularly conducted substantial business within the State of California, maintained permanent employees and offices in California, and made and is making significant sales within California. Medtronic is thus subject to personal jurisdiction in California.

19. Venue is proper in this district pursuant to 31 U.S.C. § 3732(a) because Medtronic transacts business in this district, selling and promoting its devices to multiple hospitals in this district.

IV. FACTS

A. Medtronic Illegally Promoted Implantation of CRDM Devices by Providing Kickbacks to Physicians and Researchers.

20. Medtronic used illegal kickbacks and quid pro quo arrangements to ensure that physicians would continue to implant Medtronic's devices. None of these incentives have anything to do with true scientific or medical research or with the safety of patients. These incentives include cash payments to "consultants" and "preceptors", cash payments for a "speakers bureau" and to national and regional "advisory boards" and for participation in teleconferences, post-market research, "case studies", paid travel, and paid sporting activities, as well as the other activities described herein.

21. Medtronic rewarded doctors with kickbacks for implanting large quantities of Medtronic devices. Some doctors, who implanted a large number of Medtronic devices, were given gifts including outdoor sports activities, gift cards, expensive meals, and tickets to professional sports games. Medtronic also expected sales representatives to supply some doctors with gifts of wine and alcohol, and to take them to strip clubs. Adolfo Schroeder had personal knowledge of gifts of alcohol for physicians, and of paid visits to strip clubs for physicians.

22. Medtronic established formal internal guidelines for the award of these benefits to physicians which are based entirely on the amount of implants performed by the physicians and the ability of the physician to influence other

physicians to begin implanting Medtronic devices. The recipients of these awards and benefits were selected by the Medtronic marketing department based on the recipients' ability to implant Medtronic heart devices and to influence other doctors to do so.

23. Some doctors demanded payment from Medtronic as a speaker, a researcher in order to use Medtronic devices, or demanded Medtronic pay for lunch or dinner for the physicians' entire office or the physicians' friends. Medtronic managers would generally agree to pay, and would instruct sales representatives to arrange the paid activity for the doctor. Medtronic sales representatives were then responsible for following through to ensure that Medtronic generated CRDM device sales based on the provision of the quid pro quo payment.

24. For example, Dr. Harry Balian requested the ability to make money from Medtronic as a frequent speaker in order to implant Medtronic's CRDM devices. A March 19, 2007 Medtronic "Target Update" document indicated that Dr. Balian had been speaking for Medtronic, and in return had "referred and asked for Medtronic ICD and Pacemakers" (attached hereto as Exhibit 4). In addition, a February 20, 2007 field evaluation of Adolfo Schroeder by Medtronic Regional Sales Director Gary Sterling stated about Dr. John McKenzie "We do know what he wants" in reference to Dr. John McKenzie asking for paid research studies and paid speaking engagements in order to increase his use of Medtronic devices (attached hereto as Exhibit 5).

25. Medtronic knew that its provision of kickbacks to these physicians and researchers was illegal and made efforts to conceal its illegal, fraudulent scheme by funneling some payments through 3rd party consulting organizations. Medtronic also understood that its provision of these kickbacks actually caused CRDM devices to be used for off-label purposes. Many of these devices were paid for by Medicaid, Medicare, and the TRICARE health care system for military members and their familes. Had the United States and the several States known that these

devices were used due to a fraudulent kickback scheme, they would not have provided reimbursement for these devices.

1. Medtronic Paid Physicians Honoraria, Free Travel, and Lavish Meals and Accommodations to Attend Events Promoting the Use of CRDM Devices.

26. In its efforts to promote the use of CRDM devices in patients with minor heart failure symptoms or no symptoms, Medtronic provided honoraria, free travel, and lavish meals and accommodations to key opinion leaders and other physicians to attend conferences, symposia, and other events where CRDM devices were being promoted.

27. Medtronic restaurant dinners were lavish, sporting event tickets included box suites for family and friends with no educational component, sports and recreational outings could cost several hundred dollars, and resort weekends were at expensive hotels and required little or no attendance at consultant meetings and no actual consultations. The remuneration and gifts directly took into account the volume and value of the business generated, and were only given to physicians who had used or would agree to use the Medtronic devices. The remuneration and gifts were often lavish, not modest in nature.

28. Many dinner meetings consisted of lavish dinners at local restaurants. The emphasis at some of these meetings was also on off-label uses of Medtronic devices, and hundreds to thousands of dollars worth of honoraria were paid to physicians who spoke about off-label uses at these meetings. High volume implanting doctors and local opinion leaders were the only ones targeted for invitation. High volume implanting Medicaid and Medicare doctors were often specifically targeted for invitation. At all of the events physicians were encouraged to increase their use of Medtronic devices.

29. Medtronic ensured that cash, dinners and gifts were often targeted specifically at high Medicare and Medicaid implanting doctors, to increase market

share within the Medicaid and Medicare programs, and to influence the market share status of Medtronic devices within the Medicaid and Medicare programs. In addition, cash, dinners and gifts were often targeted at high Medicaid and Medicare volume facilities in order to increase Medtronic reimbursements. Also, purchasing committee members at high volume Medicaid facilities were specifically targeted for cash, gifts, grants and dinners to purchase Medtronic devices for their inventories and increase Medtronic's reimbursements.

30. Medtronic sales representatives were instructed to distribute gifts, checks for expenses and research, invitations to lavish dinners and resort weekends, basketball tickets and other entertainment exclusively to targeted high volume implanters or referral sources in order to meet the representatives' required sales levels for bonus payouts each quarter. Medtronic sales representatives were instructed to target cardiologists who referred patients to electrophysiologists for implants, and give them gifts, buy them expensive meals, and send them on paid travel. Medtronic determined that referral cardiologists would often agree to ask for a Medtronic implant upon patient referral, if the cardiologist was given remuneration and gifts. Medtronic promoted this program because electrophysiologists would often use the preferred device of the referral cardiologist when performing the implant.

31. Part of the July 20, 2004 "game plan" for Medtronic sales reps in their Business Plan was to pay for doctors to attend dinners, lunches and pay for travel, hotel stays and lavish meals at regional and national meetings in order to increase the doctors' business with Medtronic. (attached hereto as Exhibit 6)

32. On May 24, 2007, Medtronic paid for lunch and dinner for electrophysiologists, nurse practitioners, and cardiologists at Oregon Health & Science University, including dinner at the expensive and famous Wildwood restaurant in Portland. ("AV Optimization Symposium sponsored by Medtronic", attached hereto as Exhibit 7)

33. A December 6, 2006 dinner paid for by Medtronic at the Pacific Dining Car in Los Angeles was for the nurses at Los Angeles Cardiology, and was intended to make the electrophysiologists at the clinic happy and more likely to use Medtronic CRDM devices on their patients. ("December 6th Dinner Program", attached hereto as Exhibit 8)

34. On June 21, 2007, Medtronic invited doctors to a dinner at Ruth's Chris Steakhouse to hear a talk on Device Technology within a Heart Failure Management Clinic. ("Save the Date - Ruth's Chris Steak House", attached hereto as Exhibit 9)

35. On January 22, 2007, relator Adolfo Schroeder filled out a statistics report given him by his District Sales Manager, and reported his compliance to Medtronic instructions that he had sent 5 doctors on meetings involving paid travel, more than 20 to dinners and meetings with meals, had paid support money to Dr. Leslie Saxon at USC for her Heart Failure Symposium, and had presented a dinner for doctors at the Good Samaritan hospital in Los Angeles (*See* "End of the quarter info...", attached hereto as Exhibit 10).

36. In the Medtronic 2006 TSS Plan business plan, Dr.'s Harry Rockoff and George Grifka from Metro Heart clinic in Santa Monica, California were targeted for Medtronic paid travel to an event in New York in order to achieve the "Desired Result" of "Increased adopt[ion] of Rx and MDT [Medtronic] devices". Dr. Mark Lurie and a nurse practitioner from a Torrance, California cardiology clinic were also targeted to attend a San Diego Medtronic event in January, 2006, in order to "increase buy-in to Medtronic approaches to HF [heart failure]." (attached hereto as Exhibit 11)

37. In the Medtronic 2006 TSS Plan business plan, Medtronic also targeted Dr. Seidman from Cario Medical Consult Group in Lynwood/Downey, California to receive paid travel to a Las Vegas Medtronic event in February, and have dinner with a sales rep, in order to get the clinic to increase use of Medtronic

heart failure products. The doctors at the clinic were also targeted to participate in "Case Studies", in which Medtronic paid physicians approximately $250 each time to discuss patient cases with sales reps. (attached hereto as Exhibit 11)

38. In the Medtronic 2006 TSS Plan business plan, Dr. Doshi was targeted for flying to a "State of the Art Program in Feb[ruary]", and the plan was to "Go out a day early for relationship building - 4 wheeling, Dinner and attendance of program". The reason to bring him to the fly-to event early and pay for some "4 wheeling" with him was to achieve the "Desired Result" of "Increase share with Doshi", and achieve more "Implants, access and relationships". (attached hereto as Exhibit 11)

39. In the February, 2005 Medtronic "Q3-Q4 AMP Business Plan", the Medtronic sales staff planned to "Set 6 lunch (dinner) and learns for the quarter – pretty much one per referral for the quarter" with referral physicians to increase the number of implants for the quarter. Medtronic would pay for the lunches or dinners, and in return expected a return on investment ("ROI") of between two and six patients referred for Medtronic implants in the third quarter. (attached hereto as Exhibit 12)

40. A March 19, 2007 Medtronic "Target Update" document indicated that a Physician's Assistant named Leticia at White Memorial hospital received paid travel to Miami for a Medtronic program, and in return was "pushing" the use of Medtronic CRDM monitoring devices at her hospital. (attached hereto as Exhibit 4)

41. In the March 10, 2004 Medtronic "Marketing Plan" business plan, sales reps were instructed to sell "referring cardiologists" using education, dinner, and paid travel events. Sales reps were told to ask referring cardiologists to provide the names of their "top 5 referral physicians (i.e., I.M.s, GP, OBGYNs - non-cardiologists), regardless of need or symptoms. Sales reps were instructed to "Develop and promote referral/education events" which included expensive dinners and lunches and some paid travel programs to these non-cardiology physicians. The

result of these activities is that Medtronic sales reps were required to promote Medtronic implantable devices off-label to non-cardiology physicians such as general practitioners and OB-GYNs for off-label uses for their asymptomatic patients "regardless of need or symptoms". (attached hereto as Exhibit 13)

42. The Medtronic scheme was also carried out by the making of false statements and kickbacks to non-cardiology physicians, nurse practitioners, and nurses concerning the efficacy and safety of Medtronic devices for off-label uses. In some cases, Medtronic promoted Medtronic's devices off-label to these allied healthcare professionals in order to streamline the process of implanting devices and overcome authorization requirements of Medicaid, Medicare and other insurance payers.

43. Part of the March 10, 2004 Medtronic "Market Development Plan" included instructions to sell to OB-GYN's off-label, because "many [heart failure] women are being seen by OBGYN". The objective of the off-label plan was to "drive implant referrals", and sales reps were instructed to "measure and track" the ROI of dinners and programs paid for this group of physicians, and to track "the referral process". (attached hereto as Exhibit 13)

44. The Medtronic 2006 TSS Plan business plan targeted a nurse from Apex Cardiology in Inglewood, California to receive paid travel to attend a January "Vegas program", in order to get the clinic to increase the use of Medtronic CRDM devices. Additionally, a nurse practitioner from a clinic in the Lynwood/Downey, California region was targeted for Medtronic paid travel to a January event in San Diego, in order to increase clinic usage of Medtronic CRDM devices. (attached hereto as Exhibit 11)

45. In the March 10, 2004 Medtronic "Business Plan" document, sales reps were instructed to budget appropriately to ensure funding of events and expensive dinners for doctors. However, if an event was "out of reach for the budget", then the sales reps were instructed to "work with management to justify

further investment based on ROI". (attached hereto as Exhibit 13)

46. Medtronic invited doctors and nurses to numerous weekend resort events, "drive to's" and "fly to's" that targeted, high implanting doctors. Often, high implanting Medicaid or Medicare doctors were specifically targeted for invitation.

47. Part of a Medtronic July 20, 2004 business plan was to select doctors who refer potential implant patients to the top volume implanters, and send 30 of the referral doctors to attend a regional event (paid hotel, possible paid flight), to attend a national event (paid hotel, paid flight), and to each participate in a paid lunch or dinner. The purpose for these paid trips and meals was to influence the referring physicians to refer patients for Medtronic implants, and to "create Medtronic brand loyalty with physicians". (attached hereto as Exhibit 6)

48. Part of a November 16, 2005 Medtronic business plan included instructions to increase "Access" to doctors (called "players") through paid travel including airfare and hotel stays for out of town events called PSI Programs. The business plan also included plans to fly nurse practitioners to events called "CAP II programs" (attached hereto as Exhibit 14).

49. On November 10, 2006, Registered Nurses Barbara Joachim, Cheryl De la Cuezra, Nora Dalen, and Jadranka Borgudan were registered to take a Medtronic two-day seminar at the Westin South Coast Plaza hotel, and the sales representative's customer registration sheets listed them as needing paid hotel rooms (*See* "Cardiac Devices: The HF-EP Connection", attached hereto as Exhibit 15).

50. On May 10, 2007, Dr.s Boyd, Yeretzian, and Alexanian were invited to Ruth's Chris Steak House in Pasadena, CA to hear a talk by Dr. Harry Balian on Medtronic implant devices. It was advertised as an evening of "Dinner, Delicacies and Discussion" in Pasadena. Dr. Balian was the paid speaker, but he only spoke for about five minutes, and some attendees could not hear or see him. Most of the

attendees were technicians from Dr. Balian's catheterization laboratory ("cath lab"), and he wanted Medtronic to pay for their meals so that he would get a better schedule in the cath lab (*See* "Save the Date - Ruth's Chris Steak House", attached hereto as Exhibit 16).

51. Medtronic also directed sales representatives to educate physician staffs on how to bill Medicare, Medicaid and other insurers, in effect offering unpaid work from Medtronic employees to doctor's offices. The sole purpose of this action was to increase the sales of Medtronic devices through the Medicaid, Medicare and private insurance systems.

52. For example, as part of the Medtronic 2006 TSS Plan business plan, Dr. Mehdi Zargarian was to be supported by Medtronic by paying for a "referral dinner for him and his group", to which his network of referral cardiologists and physicians would be invited to attend. The Medtronic listed "Desired Result" for the referral dinner was to "Keep flow of patients coming" in order to increase Medtronic implant sales (attached hereto as Exhibit 11).

53. The August 1, 2006 Medtronic "Project Wildfire" business plan instructed sales reps to "Build Brand Loyalty" among referral physicians by flying them on paid fly-to events with a hotel stay. The project's goal was to increase the number of device implants by increasing the referral of patients to implanting physicians. Sales reps were required to track referrals as part of the program (*See* "Project Wildfire", attached hereto as Exhibit 17).

54. Payment for dinner and other incentives to increase referrals to a physician for the use of Medtronic CRDM devices is inappropriate and illegal. According to the federal Health and Human Services Office of the Inspector General (HHS OIG), paid meals would be inappropriate if they are tied directly or indirectly to the generation of federal health care program business for the manufacturer, or for the purposeful inducement of business. *See, e.g.*, 68 F.R. 2378 "these arrangements [entertainment, recreation, travel, meals, etc.] potentially

implicate the anti-kickback statute if any one purpose of the arrangement is to generate business."

55. Medtronic representatives would frequently use lunches and preceptorships—in-kind or cash benefits to physicians—in order to gain access to the physicians' patient medical records and recommend patients for diagnosis, treatment, and implantation that resulted in increased and unnecessary claims for reimbursement from state and federal health care systems.

56. Medtronic instructed sales representatives to entice doctors to use more Medtronic implantable CRDM devices by offering doctors the Medtronic CardioSight monitoring device for free. CardioSight was a Medtronic device that could be used in the doctor's office to monitor implanted Medtronic devices. The CardioSight device could communicate with implanted CRDM devices and print out a heart failure management report. Sales representatives were instructed to entice physicians to implant more Medtronic devices by offering the CardioSight equipment to doctors for free, and by telling doctors that they could increase their practice income with CardioSight by bringing patients to their offices more often for CardioSight readings. This was an illegal offer of in-kind compensation to physicians as a "perk" and as a means for driving the implantation of Medtronic CRDM devices and associated health care system claims for reimbursement.

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2. Medtronic Proffered Money to Physicians to Participate in Promotional Activities in the Physicians' Offices.

57. In the Medtronic 2006 TSS Plan business plan, the sales reps were supposed to use "Tactics" which included paid preceptorships and "case studies" in which doctors were paid about $250 each time to discuss patient cases with sales

reps or to allow sales reps to "shadow" them during their work. Often the only reason for engaging in case studies and preceptorships was for Medtronic sales reps to find out which patients could be brought into the doctor's office for testing in order to increase sales of implant devices. Medtronic targeted 23 different doctors' offices and clinics to participate in paid Medtronic case studies. The business plan targeted specific doctors for the case studies, and listed "Desired Results" for each physician, such as "Create groundswell for Sentry implants" (attached hereto as Exhibit 11).

58. Medtronic gave doctors gift certificates to online medical supply stores or direct cash payments of up to one hundred dollars to watch a sales promotional webinar at the physicians' office. Medtronic sales representatives were instructed to bring lunch and a laptop to the physician's office, and set them up on the internet to watch the webinar during a lunch. Supposedly, the sales representative was supposed to elicit "feedback" on the quality of the presentation; however in reality, no data was typically gathered or analyzed, and the entire purpose of the activity was to pay the physician in order to increase the number of devices implanted.

3. Medtronic Concealed Some Illegal and Fraudulent Payments to Physicians by Funneling Them through Third Party Consultant Companies.

59. In order to hide illegal payments to physicians, Medtronic made many payments to doctors through the Maritz McGettigan travel company. Maritz McGettigan reimbursed travel expenses, and arranged and paid for travel including airfare and expensive hotel rooms and meals.

60. Medtronic sales reps received an email from ASI Marketing on March 13, 2006, saying that for Medtronic, ASI was "your right arm when it comes to planning consumer education seminars". The company intended to assist Medtronic run promotional events for an "elderly consumer audience" (attached

hereto as Exhibit 18).

4. Medtronic Knew Its Payments to Physicians Were Illegal Because They Were Intended for the Purposeful Inducement of Business.

61. Medtronic knew its payments to physicians were illegal kickbacks. In fact, it provided its personnel with guidelines that indicated that field employees could occasionally provide modest meals or snacks to health care professionals where the primary purpose is an informational presentation. However, Medtronic dinner events with paid speakers were often a sham, with the speaker getting paid $1,000 or more but having no real responsibility. Doctors received prepared slides from Medtronic to speak from, so that the doctors did not have to put forth any effort to prepare a presentation. Doctors often simply opened a laptop on the table at dinner with some slides on it, and then only spoke for five to ten minutes, or did not speak at all and simply enjoyed the lavish dinner with the other attendees.

5. Medtronic's Payment of Illegal Kickbacks to Physicians Actually Affected the Use of CRDM Devices in Hospitals and Cardiology Clinics

62. Medtronic's scheme to pay physicians resulted in specific sales. Medtronic, like most branded device companies, monitors the relationship of its sales to its promotional efforts over a very short timeframe; Medtronic would be concerned about a drop in sales within a certain therapeutic regime not after a year look-back, or even a quarterly look-back, but over a period of just weeks. Medtronic marketing and sales strategy documents show that at least on a quarterly basis Medtronic was tracking implant volume by physician, and tracking the percentage change in implanting habits of physicians for Medtronic devices. In addition, Medtronic tracked the ROI or return on investment of paid travel and expensive meals for physicians. Medtronic sales representatives were instructed to ask physicians for additional implants when the physicians were paid to attend a lavish dinner event, and told to track follow-up implants by the physician, and to

hold the physicians accountable if the physicians did not increase Medtronic implants. Physicians were made aware by sales representatives that the physicians would not continue to be invited to lavish dinners and resort weekends if the physicians did not remain in the high volume implanter range, and if the physicians did not implant Medtronic devices. Physicians who did not continue to implant Medtronic devices were tracked on a quarterly basis by Medtronic marketing and sales personnel, and were sometimes penalized by being taken off target lists for invitations to future lavish dinners and resort weekends.

63. For example, the Medtronic 2006 TSS Plan business plan tracked the number of "HP MDT [high-powered Medtronic] Annual Implants" for some implanting doctors in the Torrance, California region. Information was included to instruct Medtronic sales reps on which physicians in the implant doctor's referring networks should be targeted (attached hereto as Exhibit 11).

64. For example, a March 19, 2007 "Target Update" document by Medtronic indicated that a number of doctors had been given lunches and travel in return for business or referrals. Dr. Thanh Nguyen had received "several lunch in-services" for his group at Glendale Adventist hospital, and as a result he "referred pts and requested Medtronic". Dr. Martha Preciado at White Memorial had been the beneficiary of "several lunch in-services". Dr. Onkar Marwah at Glendale Memorial had received "Out of office lunches" and requested to attend paid travel events; as a result he "will always request Medtronic". Dr. Peter Fung at Glendale Memorial, Alhambra and Methodist hospitals had received lunches and "was sent to San Francisco [event] even though it was canceled". Dr. Stanley Wishner at Good Samaritan hospital received lunch in-services, and began "Using more Medtronic". (attached hereto as Exhibit 4)

65. The Medtronic February 8, 2005 "Q3-Q4 AMP Business Plan" called for flying Dr. Kaushal Tamboli to a meeting in New York, and possibly to a meeting in San Francisco, and then getting "commitment to [January] implants".

Dr. Tamboli was a physician who referred to implanting physician Anantjit Singh, and the business plan detailed efforts to increase his number of referrals for Medtronic devices to Dr. Singh. As a result of the paid travel, Medtronic expected Dr. Tamboli to refer 6 patients for implants in the 3rd quarter, and 9 patients for implants in the 4th quarter. Part of the business plan discussed the "Events, $$, people to implement the strategies" in order to get Dr. Tamboli and others to increase referrals, and set specific "Anticipated ROI" targets and anticipated "ROI Timing". The document also had a space for "ROI Status", for Medtronic sales reps to follow Dr. Tamboli and others' degree of follow-through on their commitments after receiving the paid travel benefit. (attached hereto as Exhibit 12)

66. Other physicians who were targeted for paid travel on the February 8, 2005 "Q3-Q4 AMP Business Plan" included: Dr. Chengalory Ragunathan, who would be flown to an event in New York, and was expected to deliver two 3rd quarter referrals and four 4th quarter referrals as part of his Anticipated ROI; Dr. Jerry Flor, who would be flown to an event in New York, and was expected to deliver two 3rd quarter and five 4th quarter referrals for Medtronic implants as part of his anticipated ROI. (attached hereto as Exhibit 12)

67. A March, 2006 Medtronic spreadsheet listed the top heart medication prescribers in the Los Angeles area and other areas nationwide, and targeted them for marketing activities from sales representatives (*See* FINAL HP LIST (old and new data) for TSDs Jan 29 - Los Angeles March 2006 purchases", attached hereto as Exhibit 19). A similar October, 2005 spreadsheet targeted doctors based on their heart medication prescription volume (*See* FINAL HP LIST (old and new data) for TSDs Jan 29 - Los Angeles Oct 2005 purchases", attached hereto as Exhibit 20). A master spreadsheet from January 29, 2007 targeted the high volume heart medication prescribers nationwide, and instructed specific sales representatives to market to them. (*See* FINAL HP LIST (old and new data) for TSDs Jan 29", attached hereto as Exhibit 21)

68. For example, in the Medtronic 2006 TSS Plan business plan, targeted hospitals and clinics were referred to as "Mega" and "Mini-Mega" to signify their large volume of implants. On the same spreadsheet, Medtronic kept track of the volume and market share for each type of implantable device at each facility, and tracked the percentage of Medtronic devices being used by implant physicians, who were often recipients of Medtronic paid travel, dinners, lunches, "preceptorships", and/or "case studies". (attached hereto as Exhibit 11)

69. For example, Medtronic tracked Southern California hospital and clinic implants by physician in a 2007 ROI spreadsheet called "Trending Implants - By Implant Physician - TSR". Each physician was tracked for the physician's volume of each type of implant by quarter through 2007, and each physician's implants for 2008 and 2009 were forecasted, based on historical trends as well as on the number of fly-to paid events and expensive dinners Medtronic sales staff had targeted them to attend in the future months. (attached hereto as Exhibit 22)

70. As part of the Medtronic 2006 TSS Plan business plan, Dr. Simon Kangavari was targeted for a "state of the art program in Feb. ... dinner, along with a rep", and "another power lunch with key APEX docs and VIP [company executive or Medtronic 'champion' doctor]". The "Desired Results" of these expensive, paid meals would be to "Increase/maintain share with Kang[avari]", and to "Increase adoption" of Medtronic products. (attached hereto as Exhibit 11)

71. Medtronic sales representatives provided gift cards, meals and other favors for physician members of purchasing committees and their staffs, including purchasing committeeswhich effected large Medicaid and Medicare patient populations, such as hospitals with large Medicaid and Medicare populations. Medtronic management directed sales staff to invite purchasing committee members to lavish dinners, resort weekends and basketball games and other entertainment. Medtronic management directed sales staff to request purchasing committee members participate in "preceptorships" or shadowing, but the purpose

of the preceptorship was merely to confer a cash benefit to the physician in order to sway her implanting habits and purchasing decisions. Medtronic management arranged payment of large grants to influential purchasing committee members in order to purchase Medtronic devices into inventory.

72. Medtronic also instructed physicians' office staff and clinic personnel to maximize Medicaid and Medicare billing. Medtronic field representatives gave billing seminars, in which the Medtronic representatives suggested additional billing codes that could be submitted in conjunction with certain procedures. The field representatives also reviewed prior billings for some facilities, and suggested additional billings that Medicaid or Medicare were known to pay for without question.

73. For example, a January, 2006 Medtronic guide to help doctors build "an Effective Heart Failure Clinic" provided 43 pages of instructions on which ICD-9 codes to use when billing for a CRT or ICD implant. The guide also gave suggestions on additional codes to use in order to maximize billings when implanting devices. ("Medtronic 2006 Physician Coding", attached hereto as Exhibit 23)

74. In the February, 2005 Medtronic "Q3-Q4 AMP Business Plan", the Medtronic sales staff planned to show Dr. Promad Multani how to "Break the bank". The Medtronic representatives planned to meet with him to "Emphasize realistic patient and econ[omic] numbers" he could realize from referrals for Medtronic implants, and to "Show DRG payments for Downey and St. Francis" - show him how other facilities were maximizing their billings. As a result, Dr. Multani was expected to deliver an ROI of two Medtronic implant referrals in the 3rd quarter, and 3 Medtronic implant referrals in the 4th quarter. (attached hereto as Exhibit 12)

75. Part of a Medtronic July 20, 2004 business plan was to select doctors who refer potential implant patients to the top volume implanters and educate them

on the "Economics of devices", and "Reimbursements for devices" in order to show them how to maximize reimbursements and grow their clinic income (attached hereto as Exhibit 6)

76. Medtronic sales reps were given a copy of a 2006 Cambridge Heart "Heartwave II" System ROI sheet, showing what profits physicians could make off of this 3rd party testing device when sold in combination with Medtronic devices. The profit analysis indicated how much profit doctors could make per "MTWA" test ($289), and how much profit per year (over $120,000). The Medtronic sale reps were instructed to promote this device to physicians in order to show doctors how to maximize Medicare billings with Medtronic devices and 3rd party accessory devices (attached hereto as Exhibit 24)

77. Medtronic also instructed its sales representatives to violation patients' privacy by reviewing patient charts at doctors' offices to select patients for receiving implantable devices. Sales representatives were given pre-printed post-it flags to put on patient charts that the Medtronic representatives felt should be given an implant. Medtronic trained its sales representatives to flag all charts with an Ejection Fraction ("EF") score of 40% to 45%, even though the CRDM devices were not indicated for patients with an EF score in excess of 35%. Medtronic trained its sales representatives to present these charts to doctors and ask them directly to implant or refer for testing. Medtronic also directly marketed to patients and their referral physicians in order to increase the number of devices implanted.

78. Adolfo Schroeder was told at a July, 2006 Medtronic two-day sales conference in Thousand Oaks, California attended by attended by personnel from throughout the Southern California region, "you may not agree this pt. (80+) is candidate for ICD but what about CRT to improve their QOL [quality of life], see grandkids, play golf etc."; "CRT therapy - Don't let doctor make decision for pts." (handwritten note from the conference, attached hereto as Exhibit 25)

79. A September 18, 2006 Medtronic sales representative training manual stated that part of the job of the sales rep was to "Influence referring physicians and clinical personnel to appropriately identify patients who could benefit from device-based therapies". Sales reps were further instructed to constantly evaluate the patient identification processes at each clinic and hospital "to achieve device adoption that achieves sales goals and objectives". (attached hereto as Exhibit 26)

80. A December 1, 2006 PowerPoint presentation by Dr. Kevin Inwood was given to Adolfo Schroeder by Medtronic sales personnel to use with doctors. The presentation promoted the off-label indication for Medtronic ICD devices for patients with EF scores up to 40%, and also threatened doctors that they might face malpractice liability if they failed to identify patients falling within these parameters and evaluate them for an implant. (*See* "The Bottom Line", attached hereto as Exhibit 27)

81. A February 20, 2007 Medtronic template letter to referral physicians stresses that their patient "has been identified as being potentially at high risk for sudden cardiac death, and may benefit from placement of an implantable cardioverter defibrillator and/or cardiac resynchronization therapy". The letter was part of a "turn-key" heart failure clinic business solution that Medtronic promoted to cardiologists and hospitals. Sales representatives were trained to show cardiologists how the physicians could use Medtronic pre-printed medical forms and templates to run a heart failure clinic, and to show them how much profit the physicians could make off Medicaid, Medicare and other payers if the physicians implanted Medtronic CRDM devices. Medtronic sales representatives were also coached at training meetings to pressure doctors into believing that the physicians would face the liability of malpractice suits if the physicians did not implant Medtronic CRDM devices in a broad patient population. (*See* "SCA Screening Letter", attached hereto as Exhibit 28)

82. A March 19, 2007 Medtronic "Target Update" document indicated that Doctors Gary Conrad and R. Fernando Roth in Pasadena had received "lunch in-services" for their staff paid by Medtronic. In return, the physicans were letting Medtronic sales representatives work "with Roth and Hospital to educate echo staff to flag potential candidates for device therapy", and work with the "echo tech in office (Kimberly) to also better identify potential patients". (attached hereto as Exhibit 4)

B. Medtronic Illegally Engaged in the Promotion of Cardiac Devices for Off-Label Use.

83. New pharmaceutical drugs or medical devices may not be marketed in the United States until the sponsor of the drug or device has proven to the Food and Drug Administration (FDA) that the drug or device is safe and effective for specific indications at specified dosages (if applicable). The indications and dosages (if applicable) approved by the FDA are set forth in the product's labeling, the content of which is also approved by the FDA. Although it is not unlawful for physicians to use devices for indications or at dosages different than those set forth in a product's labeling, The Food Drug and Cosmetic Act prohibits medical device companies from marketing or promoting approved devices for uses other than those set forth in the device's approved labeling. This regulatory scheme protects patients and consumers by insuring that medical companies do not promote drugs or devices for uses other than those found to be safe and effective by an independent, scientific governmental body.

84. The Medicaid and Medicare programs also rely on the FDA's findings regarding what uses for approved drugs and devices are safe and effective. The Omnibus Budget Reconciliation Act of 1990 limited Medicare reimbursement for drugs or devices to "covered outpatient drugs" 42 U.S.C.§ 1396r-8(k)(2)(A). Covered outpatient drugs and devices only include drugs and devices used for "medically accepted indications." A medically accepted indication is a use which

has been approved by the FDA or one which is supported by specific compendia set forth in the Medicare statutes. Until August, 1997 none of the compendia referenced in the statutes supported off-label usage of any approved drugs or devices. Even after August 1997, off-label usage was significantly restricted.

85. Off-label use of a medical product refers to the prescription or use of a product in a manner not approved by the FDA. Since Congress passed the Food and Drug Administration Modernization Act ("FDAMA") in November 1997, manufacturers may provide off-label studies to the medical community only if certain conditions are met. Moreover, federal law prohibits manufacturers from promoting off-label uses through physician studies when the investigating physician is not truly independent or impartial, as well as when the physician is in fact an agent of the manufacturer based upon significant financial relationships. *See* 21 U.S.C. §§ 360aaa *et seq.*

86. Whether a device is FDA-approved for a particular use will largely determine whether payment for that device will be reimbursed under the federal and state Medicaid and Medicare programs. Thus, the off-label use of such devices is not eligible for reimbursement under Medicaid. Likewise, many state Medicaid agencies intend not to reimburse for devices for off-label purposes because the agencies do not wish to spend money on devices not recognized as medically necessary in sources specified by federal law. CRDM devices were not eligible for reimbursement from federal or state Medicaid or Medicare programs when prescribed for use in patients with minor heart failure symptoms or no symptoms.

87. Medtronic has known that its ICD devices were only approved for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. Medtronic has also known that its CRT-D devices were only approved for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias and for the reduction of the symptoms of moderate to severe heart

failure (NYHA Functional Class III or IV) in those patients who remain symptomatic despite stable, optimal medical therapy and have a left ventricular ejection fraction ("EF") less than or equal to 35% and a QRS duration of =130 ms. Nevertheless, Medtronic has pushed far beyond this range of approved use in its CRDM promotional activities.

88. Medtronic's conduct caused physicians to submit billings for CRDM devices that were ineligible for reimbursement under Medicaid and Medicare because the devices were used for an off-label purpose. Further, Medtronic's conduct caused physicians, hospitals, and cardiac clinics to purchase and use CRDM devices. Such purchases and use were not eligible for reimbursement under Medicaid and Medicare because the devices were for an off-label use. Medtronic thus caused the submission of false claims for payment of money under the federal Medicaid and Medicare programs and state Medicaid programs.

89. Additionally, the military's payments to cover the use of CRDM devices for patients with minor heart failure symptoms or no symptoms were not eligible for coverage under the TRICARE health care plan for members of the military and their families (formerly known as CHAMPUS), or through direct purchasing by the military. The Department of Defense will generally pay for the costs only of "proven" devices, meaning devices that have been found to be "safe and effective" by the FDA. 32 C.F.R. § 199.4(g)(15)(i)(A). TRICARE will pay for off-label use of a device only if the use is determined to be a "medical necessity" and if the program can determine that the off-label use is "safe and effective and in accordance with nationally accepted standards of practice in the medical community." *Id.* TRICARE will not pay for a device unless "reliable evidence shows that the medical treatment or procedure has been the subject of well-controlled studies of clinically meaningful endpoints." 32 C.F.R. § 199.4(g)(15)(i)(C). The studies Medtronic supported to promote the use of CRDM devices off-label did not meet these standards. Had TRICARE known this, it

would not have covered or reimbursed the off-label use of CRDM devices.

90. In limited situations, investigational devices may be used by the military. However, whenever a member of the armed forces receives a device unapproved for its applied use, the member must be given notice and consent to such use. 10 U.S.C. § 1107. In order to waive consent for the purposes of using such an "investigational device" in battle, the Secretary of Defense must request a waiver from the President. No such waiver was requested for CRDM devices.

91. As described in this Complaint, Medtronic has, since 2002 through the present, knowingly and intentionally violated the regulatory schemes described above in its marketing of Medtronic products. Medtronic knew or should have known that thousands of physicians (chiefly through their hospitals under applicable diagnostic related groups [DRG's]) would routinely and necessarily file false claims with the federal government when the physicians sought federal reimbursement for Medtronic CRDM devices and related Medtronic products. But for Medtronic's actions most, if not all, of the false claims for the purchase of Medtronic products would never have been filed. Although in some cases the physicians did not directly contract with the federal government, Medtronic was the indirect beneficiary of all of the false claims described in this Complaint.

92. While all on-label and off-label sales made or effected by the health care providers receiving unlawful kickbacks or engaging in improper self-referral cause false claims to be filed, the unlawful promotion of off-label uses of Medtronic products provides an additional, independent, and, under the circumstances, far more urgent basis for the government to interdict this activity—the public health is at risk.

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1. Medtronic Trained Technical Field Experts and Sales Representatives to Promote Off-Label Use of Medtronic CRDM Devices.

93. The Medtronic sales representatives were trained to use knowingly off-label information to persuade physicians to use Medtronic devices. Medtronic trained and directed sales staff to tell doctors that Medtronic devices are effective for a variety of off-label claims; none of which were indications which the FDA had approved for Medtronic devices.

94. Medtronic held national sales meetings once a year, where it provided off-label sales training to both sales representatives and technical field experts in the uses of Medtronic CRDM devices for patients with mild or no symptoms of heart failure. The sales representatives and technical field experts were also taught how to approach physicians about these off-label uses of Medtronic CRDM devices at teleconferences and at local and regional meetings.

95. Medtronic trained its technical field experts to promote its CRDM devices as particularly effective for preventing sudden cardiac arrest in patients with mild or no symptoms of heart failure as a method of "primary prevention" of sudden cardiac arrest, even though such "preventative" use of CRDM devices for patients with mild or no symptoms of heart failure was not approved by the FDA.

96. At a September 18, 2006 sales training meeting, Medtronic trained sales representatives to "open up a conversation with your referral customers" on the off-label uses of Medtronic ICD devices for off-label uses in mildly symptomatic patients for whom the Centers for Medicaid and Medicare Services (CMS) had not agreed to reimburse. The document states "Medtronic Confidential" on every page, and says "Currently, we are working with CMS to create reimbursement for this patient population. In the interim, we want to continue to push ICD referrals for the currently indicated and reimbursed patients, including MADIT-II". Medtronic trained the sales representatives to begin conversations with doctors about the off-label uses of ICD's for mildly symptomatic patients - "This conversation guide provides a potential road map to having conversations with both your referral and implanting physicians on the SCD-HeFT results, primary

prevention evidence, and identifying and handling the barriers to referrals and implantation" (*See* "Medtronic SCD-HeFT Conversation Guide and Handling Primary Prevention Barriers", attached hereto as Exhibit 29)

97. On August 1, 2006, at its "Project Wildfire" sales training meeting for its sales representatives and technical field experts, Medtronic instructed its employees to work to "expand the reach of our market development activities beyond therapy sales". Medtronic's promotion of CRDM devices for non-therapeutic sales, however, is illegal. ("Project Wildfire", attached hereto as Exhibit 17)

98. Medtronic set goals for the sales representatives to promote the use of CRDM devices off-label, and to develop "key opinion leaders" or KOLs who would support and promote the use of Medtronic CRDM devices off-label. For example, a March 10, 2004 Medtronic business plan targeted non-cardiac physicians such as OB-GYNs for off-label promotion of CRDM devices. Sales representatives were instructed to "drive implant referrals" from these non-cardiac physicians, and to push for the referral of patients "regardless of need or symptoms". Sales reps were instructed to push for the referral of patients for "primary prevention" - meaning patients who had not yet had a sudden cardiac arrest event, even thought Medtronic was aware of studies that showed more than 75% of the devices would never deliver a therapeutic shock. (Marketing Plan, attached hereto as Exhibit 13)

99. One undated CME presentation funded by Medtronic promoted the use of implants for patients with a higher than indicated EF level (less than or equal to 40%), and for asymptomatic patients. (J. Paul Mounsey, "Management of the Patient at Risk for Cardiac Arrest", attached hereto as Exhibit 30).

100. These educational programs are some of the many that Medtronic paid for to promote CRDM device implants off-label to doctors in hospitals and clinics nationwide. In fact, Adolfo Schroeder's records show dozens of paid travel and

educational events for cardiac and other physicians at these facilities, all intended to establish a relationship in which Medtronic sales representatives could promote CRDM devices for off-label uses. For example, a July 20, 2004 Los Angeles Medtronic business plan targeted 30 local physicians to attend one national event and one regional event each, with airfares, hotels and meals to be paid by Medtronic. Such lists were generated by the sales district during their district business planning processes. ("July 20, 2004 TSS Plan", attached hereto as Exhibit 6)

101. As part of their scheme to promote CRDM devices for off-label use, Medtronic trained its sales representatives and technical field experts to prompt physicians to ask questions about Medtronic CRDM devices. For example, although Medtronic told its sales representatives that they could not talk about off-label uses of CRDM devices unless a physician asked a specific question about the product, sales representatives were trained to describe particular patient profiles that would fit an off-label use, and use probing questions to elicit a discussion with the physician about that off-label use. Sales representatives could talk about the clinical research in which Medtronic was engaged, including Medtronic clinical research trials on the use of CRDM devices in patients with mild heart failure symptoms or no symptoms.

102. When a physician then asked a question about off-label uses of Medtronic CRDM devices, the technical field expert was allowed to respond, and was trained to provide the physician with further information on the off-label uses of the devices. In other words, after a sales representative prompted a question about CRDM devices from a physician, he would then direct Medtronic's technical field experts to send the physician a Medtronic document (via fax, e-mail or postal service), or share a presentation on the off-label use of the CRDM devices in mildly symptomatic or asymptomatic patients.

103. Although Federal regulations did not permit Medtronic to promote unapproved uses of their devices, Medtronic was permitted to distribute publications created by "third parties" that described results of off-label uses of Medtronic devices, if such material was distributed in response to non-solicited requests from physicians. Medtronic decided to exploit this narrow exception by creating events and programs that would allow special Medtronic employees and independent contractors under Medtronic's control to promote off-label usage under circumstances that would allow Medtronic to deny, wrongfully, that it had solicited off-label usage.

104. For example, Medtronic sales representatives were given a February, 2007 presentation to hand to physicians that included instructions at the top to screen patients with an Ejection Fraction score (EF score) of less than or equal to 40% for possible sudden cardiac arrest and need for possible implantation with a CRT or ICD device, when FDA indications only allowed symptomatic patients with an EF less than or equal to 35%, along with other factors, to be implanted. ("Identifying Patients at High Risk for Sudden Cardiac Arrest in Your Practice", attached hereto as Exhibit 31)

105. Medtronic sales reps were also instructed to show a February 23, 2007 document called "Sudden Cardiac Arrest (SCA) Provider Fact Sheet". The document stated that "Patients with mild heart failure should not be considered at lower risk for SCA", and was an effort to increase the number of off-label implants for asymptomatic patients. (attached hereto as Exhibit 32)

106. For example, a Medtronic "Therapy Sales Representative (TSR) Phase I Training" manual from September 25-29, 2006 stated that the company could benefit from "growing indications" for ICD therapy by promoting single chamber ICD devices to patients with an expanded range of symptoms. (attached hereto as Exhibit 33)

2. Medtronic Sponsored Seminars, Symposia, and Other Continuing

Medical Education Programs that Promoted the Use of CRDM devices in Mildly Symptomatic or Asymptomatic Patients.

107. Medtronic also sponsored seminars and events for physicians and their patients, all with the purpose of promoting CRDM devices for use in patients with mild or no heart failure symptoms. Medtronic particularly targeted cardiologists with these events in order to encourage them to refer more patients and to expand the use of Medtronic CRDM devices to treat asymptomatic and mildly symptomatic heart failure patients off-label.

108. Specifically, as part of its scheme to promote CRDM devices widely for use to treat asymptomatic and mildly symptomatic patients, Medtronic sought out influential cardiologists and electrophysiologists and proffered kickbacks to them in return for conducting research and implementing policies promoting the use of CRDM devices in those off-label cases. As set forth below, most of this "research" consisted of paying a physician to implant a specific Medtronic device and report some simple findings. The Medtronic marketing department made the decisions on which doctors to pay to do case studies and be involved in research protocols based on their CRDM device implant volume, showing that Medtronic was not paying those doctors for a legitimate research purpose. In effect, Medtronic paid these influential physicians to implant their patients with Medtronic devices in order to expand their market share. Medtronic also paid these "Key Opinion Leaders" and "Champions" to promote the use of CRDM devices at seminars and other events for referring cardiologists, clinic staff, and implanting devices in patients.

109. The Medtronic "Champions" included Dr. John McKenzie from Glendale, California, who participated in at least two paid Medtronic studies and was listed as a "player" on a November 16, 2005 business plan ("11-16-05 In a Nutshell Plan", attached hereto as Exhibit 14); Dr. Mayer Rashtian from

Huntington Memorial Hospital in Pasadena; Dr. Vivian Tan from Glendale, California; Dr. Leslie Saxon from the University of Southern California, who was paid consultant fees and research fees from Medtronic according to a January 16, 2007 study she co-wrote ("Effects of Cardiac Resynchronization Therapy With or Without a Defibrillator on Survival and Hospitalizations in Patients With New York Heart Association Class IV Heart Failure", attached hereto as Exhibit 34); Dr. Charles Swerdlow from UCLA; Dr. Nigel Gupta and Dr. Michael Wong with the Kaiser Permanente Medical Group, Los Angeles.

110. Another means by which Medtronic paid kickbacks to physicians for the promotion of off-label use of Medtronic devices was through programs billed as Continuing Medical Education seminars (CME). These conferences and seminars were set up to appear to qualify for an exception to the FDA's off-label marketing restrictions which permit physicians to learn about off-label uses of devices at independent seminars. Such seminars, however, must be truly independent of the device companies. The device companies may make "unrestricted grants" for the purpose of a seminar, but may not be involved in formulating the content of the presentations, picking the speakers or selecting the attendees.

111. None of these requirements were observed with regard to the CME seminars sponsored by Medtronic for the promotion of Medtronic devices. While Medtronic retained third-party organizations such as ASI Marketing and Maritz McGettigan travel company to present the event seminars and pass on payments to doctors, Medtronic retained control of virtually every aspect of these events, and the seminar companies obtained Medtronic's approval for all content presented at the seminars. Medtronic also paid all expenses, including all of the seminar company's fees.

112. More importantly, Medtronic paid for these so-called continuing medical education programs and designed them to instruct physicians on how to justify off-label use of Medtronic devices.

113. One undated CME presentation funded by Medtronic promoted the use of implants for patients with a higher than indicated EF level (less than or equal to 40%), and for asymptomatic patients. The physicians were told that patients with an EF less than or equal to 40% who were asymptomatic were given an implant in a recent study. In actuality, CRDM implants are not indicated for asymptomatic patients or for patients with an EF score greater than 35%, among other requirements. ("Ventricular Arrhythmias: Management of the Patient at Risk for Cardiac Arrest", attached hereto as Exhibit 30)

114. On March 30, 2007, Medtronic paid for a Continuing Medical Education seminar to be broadcast that instructed physicians on how to justify using an ICD off-label for patients above the 35% EF level. (William T. Abraham, MD, "New Guidelines for Primary Prevention of Sudden Cardiac Death in HF: What the Future Holds and the Role of Primary Care Physicians", attached hereto as Exhibit 35)

115. Medtronic hired third party contractors to put on dinner events, to which high volume implanting physicians were selected by Medtronic representatives, managers, and executives to attend, where the implanting physicians received honorariums. Some of these physicians were picked based on their volume of Medicaid and Medicare business. All aspects of these events were controlled by Medtronic, including the preparation of slides for the "independent" speakers. All costs were paid by Medtronic, and payments funneled through the third party contractors.

116. Dinner events were held at lavish restaurants, and often had almost no educational component at all. On many occasions the speaker would be a doctor who received $1,000 or more to attend the meal, and who received the speaker fee as a benefit for using a high volume of Medtronic devices. The speakers were given slides by Medtronic to use at the dinners, and did not have to prepare their own. Speakers would sometimes set up a laptop on a table with a PowerPoint

presentation running, but not give the presentation and just have dinner with other doctors. Medtronic did not always require doctors to sign in for dinner on sign-in sheets.

117. Medtronic also founded a speaker's bureau, another method to make large and numerous payments to physicians who recommended Medtronic devices at teleconferences, dinner meetings, consultant meetings, educational seminars and other events. These speakers repeatedly gave short presentations relating to Medtronic devices for which they were paid anywhere from several hundred to several thousand dollars per event, commonly $1,500 or more. The presentations were effectively "canned" content provided by Medtronic. Medtronic targeted opinion leader physicians, most of whom were high volume implanters and were influential. The payments that these doctors received were far in excess of the fair value of the work that they performed for Medtronic. Speakers who most zealously advocated Medtronic devices were hired most frequently for speaking events, notwithstanding the fact that many of these events purported to be independent medical education seminars where independent information was supposed to be delivered.

118. Medtronic also sponsored continuing medical education programs that promoted the use of CRDM devices off-label for mildly symptomatic or asymptomatic patients.

119. FDA marketing restrictions permit physicians to learn about off-label uses of devices at independent seminars. Device companies may make "unrestricted grants" for the purpose of supporting a seminar, but may not be involved in formulating the content of the presentations, picking the speakers or selecting the attendees. Medtronic did not observe any of these requirements with regard to the seminars and symposia it sponsored for the promotion of "off-label" uses of CRDM devices.

120. For example, Medtronic provided speaker slides made by Medtronic to physicians making off-label presentations on CRDM devices. Dr. Michael Field used Medtronic prepared slides in his October 5, 2006 "Know Your EF Talk" presentation at the Longwood Medical Area ICD Support Group, which was supported by Medtronic. In the presentation, Dr. Feldman stated that patients with an EF score as high as 40% or 50% should be evaluated for a CRDM device implant. (*See* Dr. Michael Field, "Know Your EF", attached hereto as Exhibit 36)

121. Part of the Medtronic scheme included paying for "Know Your EF" presentation days for patients. These health fairs were run at hospitals and clinics for high volume implanters and referral physicians who were willing to use Medtronic implants. The purpose of these events was to promote more implants directly to consumers, promote implants off-label, and help clinics and hospitals sign more people up for Medtronic heart implants. There was no legitimate medical need for patients to "know their EF score", as it could be variable throughout the day and the week, and by itself was not an indicator of a need for a CRDM implant or any other treatment. Medtronic, however, promoted the "Know Your EF" events in order to promote implants to new potential patients and to sell additional CRDM devices. Medtronic commonly paid hundreds or thousands of dollars to send invitations directly to patients, select which patients to invite, pay for food and EF mobile testing vans to conduct the event, and paid for other promotional activities. These "Know Your EF" days represented provision of services by Medtronic to eliminate expenses that the physicians and facilities would have otherwise incurred, and had independent value to the physicians and facilities. Medtronic pushed clinics and doctors to run "Know Your EF" programs, because the Medtronic off-label scheme included promoting the idea to patients that the EF score alone would indicate the need for a CRDM device implant. The arrangement was illegal because it was tied directly to the generation of state and federal health care program business for Medtronic.

122. A September 18, 2006 Medtronic tactical sales plan stressed the goals to "Foster Brand Loyalty" and to create "Primary Prevention Market Expansion". The primary prevention market consisted largely of patients whose heart failure symptom severity did not meet the required level of indications, and who had not suffered a previous sudden cardiac arrest. Despite the fact that more than 75% of patients implanted with ICD devices never receive a therapeutic shock, Medtronic marketed heavily for this population in order to expand revenue from state and federal health care systems. Medtronic was going after the "primary prevention" market in order to increase the number of devices implanted beyond those patients who had already had a sudden cardiac event, to those who may have one in the future. The "tactics" sales reps were to use included the "identification of patients eligible for ICDs", and the "Know your EF program", for which Medtronic sales reps were supposed to get the facility to mark the EF score for each patient (attached hereto as Exhibit 26).

123. Medtronic instructed sales representatives to personally review patient charts in friendly doctor's offices, and to flag patient charts for those that the sales representative felt should receive an implant. The sales representatives were then expected to follow-up, and get the doctor's offices to pull those patients in for evaluation, in order to increase the number of CRDM device sales on a monthly or quarterly basis in their territory, resulting in increased claims for reimbursement under state and federal health care systems.

124. Medtronic trained its sales representatives to ask doctors to re-evaluate the Ejection Fraction score of a patient (EF Score), a cardiac blood flow measure that is used as one several indicators for a CRDM device implant. Medtronic trained its sales representatives at national and regional sales meetings to ask doctors to reduce the EF score in order to meet criteria for implanting a CRDM device in a patient, and to tell the doctor to base it on the known 5% to 10% variability in EF score measurement. Medtronic also coached sales representatives

to tell doctors that they would likely be liable for malpractice if a patient was not referred for an implant and subsequently had a sudden cardiac arrest. In this way, Medtronic attempted to pressure doctors to implant their CRDM devices in patients in order to boost sales and revenue.

125. For example, Medtronic sponsored an undated "Know your EF score" patient event at Desert Cardiology Center which promoted the testing of patients for EF scores above 35%, which is off-label for ICD implants. Events like these led to unnecessary diagnosis, treatment, and/or implantation, resulting increased claims for care in state and federal health care systems. (*See* "Indications for patients Eligible for an ICD", attached hereto as Exhibit 37)

126. A common means by which Medtronic funneled illegal payments to physicians to encourage them to implant off-label was through "consultant" meetings or by inviting them to join paid marketing "Advisory Boards". Under this guise, Medtronic recruited physicians to dinners or conferences and paid them to hear presentations about off-label uses of Medtronic devices. Under the guise that these doctors were acting as "consultants", Medtronic sometimes had the doctors sign sham "consulting agreements". At these meetings, Medtronic would give these doctors presentations related to Medtronic devices, sometimes regarding off-label usage. Presentations would be made by Medtronic employees or physician speakers hired by Medtronic for the purpose of promoting Medtronic devices.

127. In order to conceal its involvement in these seminars and symposia, Medtronic also often retained third-party organizations such as ASI Marketing to arrange the events, and the Maritz McGettigan travel company to arrange paid travel and hotels for doctors. Maritz McGettigan often passed on payments for travel and reimbursed expenses from Medtronic. If the payments had had a legitimate educational purpose, Medtronic would have paid the doctors directly, rather than sending them through Maritz McGettigan.

3. Medtronic Provided Financing and Other Support for Questionable Research to Support and Promote the Use of CRDM Devices in Patients with Minor Heart Failure Symptoms or No Symptoms.

128. Medtronic engaged in a researching and publishing campaign under which it paid physicians to engage in off-label studies of CRDM devices in mildly symptomatic or asymptomatic patients. These studies were heavily influenced by bias, since the physicians were paid by Medtronic; the research was often coordinated by Medtronic; and in many cases, Medtronic employees were included as researchers on the projects. In sum, Medtronic deliberately pursued a scheme under which it paid for biased research and studies to support the use of CRDM devices off-label in mildly symptomatic or asymptomatic patients.

129. On July 20, 2004, as part of a Medtronic TSS business plan, the sales reps were instructed to find doctors who would be willing to take money to run a case study with Medtronic devices on their patients. Doctors were asked to accept thousands of dollars in payments to enroll their patients in Medtronic-paid research studies, including "ASSESS", and "RESTORE", and others. Medtronic made clear its intention to promote these research studies as a financial benefit to induce additional implant volumes by instructing the sales reps to target and develop doctors for inclusion in the studies. The plan was intended to "Drive device adoption", "build strong referral relationships", and "foster brand loyalty" (attached hereto as Exhibit 6)

130. Medtronic also ran a number of nationwide studies which engaged a large number of investigators, each of whom enrolled a few patients each, and for which doctors were remunerated up to several thousand dollars per enrolled patient in order to create brand loyalty with the physicians, often for off-label uses.

131. For example, in the February, 2005 Medtronic "Q3-Q4 AMP Business Plan", the Medtronic sales staff planned to pay for Dr. Jerry Flor to attend a fly-to

program in New York, and gain his "commitment to refer SCD-HeFT [Medtronic funded implant study] patient in January". Medtronic routinely paid physicians between $1,000 to $3,000 to refer each patient for "research", and some doctors refused to use Medtronic implantable devices unless the doctors were paid for implanting them as part of "research" (attached hereto as Exhibit 12)

132. Medtronic's research and publication campaign had a clear purpose: to support and promote the off-label use of CRDM devices for mildly symptomatic or asymptomatic patients.

133. Indeed, independent studies based on randomized, controlled clinical trials reveal that in this context, CRDM device therapy in patients with minor heart failure symptoms or no symptoms has not shown the level of effectiveness claimed in Medtronic promotions. In fact, according to the scientific literature, over 75% of Medtronic ICD devices may never deliver a therapeutic shock, while over 17% deliver inappropriate shocks, greatly increasing the risk of death (*See* Dr. Gust H. Bardy, et al, "Amiodarone or an Implantable Cardioverter-Defibrillator for Congestive Heart Failure," The New England Journal of Medicine, Jan. 20, 2005, attached hereto as Exhibit 1).

C. Medtronic Promoted CRDM devices for Use in Patients with Minor Symptoms of Heart Failure or No Symptoms of Heart Failure Even in the Face of Mounting Evidence of Harm.

134. Medtronic continued to promote CRDM devices for use in patients with minor heart failure symptoms or no symptoms, even in the face of evidence that such use led to an increased risk of inappropriate shock and eventual death. In fact, upon information and belief, Medtronic continues to promote CRDM devices for off-label use in patients with minor heart failure symptoms or no symptoms in the same manner as set forth in this Complaint today.

135. A 2008 study published in The New England Journal of Medicine noted that 17.4% of persons with a Medtronic implantable cardioverter defibrillator

(ICD) received an inappropriate shock, and that for all shocked patients, there was a significant increase in the rate of death due to progressive heart failure compared to patients who received no shock (*See* Dr. Jeanne E. Poole, et al, "Prognostic Importance of Defibrillator Shocks in Patients with Heart Failure," The New England Journal of Medicine, Sep. 4, 2008, attached hereto as Exhibit 2).

136. For example, a July 22, 2008 continuing medical education presentation by Dr. Eric Prystowsky indicated that implantable CRT and ICD devices were known to cause inappropriate shocks to the heart in 25% to 30% of patients (*See* "Utilization of ICD Therapy", attached hereto as Exhibit 38).

137. Given these risks, it is difficult to see how the benefits of using CRDM devices for patients with only minor symptoms of heart failure or no symptoms outweigh the risks.

COUNT ONE

FEDERAL FALSE CLAIMS ACT VIOLATIONS BASED ON THE PAYMENT OF KICKBACKS (31 U.S.C. § 3729)

138. Relator re-alleges and incorporates the allegations in paragraphs 1-137 as if fully set forth herein.

139. Medtronic's payment of kickbacks to physicians and other health care providers violated the Medicaid Anti-Kickback statute and other statutes and regulations controlling the payment of governmental employees and military personnel and caused false claims to be submitted to the federal government. Because the Medicaid Anti-Kickback statue is a critical provision of Medicaid, compliance with it is material to the government's treatment of claims for reimbursement. Had the United States and the several states known that CRDM devices had been implanted because physicians had been paid kickbacks by Medtronic to do so, neither the United States nor the States would have provided reimbursement for these device implants. As the United States and the States were

unaware of the illegality of the claims, and in reliance on the accuracy and legality thereof, made payment upon the false or fraudulent claims, the United States and the States were damaged.

140. The kickbacks described herein are strictly illegal and have had the direct effect of greatly increasing the amount of CRDM devices procured and used by the government and under the auspices of government programs. The kickbacks have had the indirect effect of increasing the amount of money spent by the federal government and the states for reimbursement of devices covered by Medicaid, Medicare, and TRICARE. The payment of these kickbacks represents the inducement of federal payments through a pattern of fraudulent conduct and constitutes false claims within the meaning of 31 U.S.C. § 3729.

COUNT TWO

MEDTRONIC'S PAYMENT OF KICKBACKS AS CONSPIRACY TO SUBMIT FALSE CLAIMS (31 U.S.C. § 3729(A)(3))

141. Relator re-alleges and incorporates the allegations in paragraphs 1-140 as if fully set forth herein.

142. Medtronic combined, conspired, and agreed together with physicians and others to defraud the United States by knowingly causing false and illegal claims to be submitted to the United States for the purpose of having those claims paid and ultimately profiting from those false claims. Medtronic committed other overt acts set forth above in furtherance of that conspiracy, all in violation of 31 U.S.C. § 3729(a)(3), causing damage to the United States.

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COUNT THREE

FALSE CLAIMS ACT VIOLATIONS FOR CAUSING SUBMISSION OF OFF-LABEL BILLS (31 U.S.C. §3729)

143. Relator re-alleges and incorporates the allegations in paragraphs 1-142 as if fully set forth herein.

144. By presenting physicians with false information about off-label uses of CRDM devices and encouraging physicians to implant CRDM devices for such uses and procure the devices for such uses which were not approved by the FDA or any relevant device compendium, Medtronic caused physicians and facilities to submit numerous bills for CRDM devices that were ineligible for reimbursement under Medicaid, Medicare, and TRICARE because the devices were used for an off-label use. Medtronic also caused the procurement of CRDM devices for off-label uses. Such procurement should not have been paid for or reimbursed by Medicaid, Medicare, or TRICARE because it was for an off-label use. Thus, Medtronic knowingly caused such physicians and healthcare facilities expressly or impliedly to make false certifications about the CRDM device's indications and efficacy. Medtronic therefore caused the submission of false claims for payment of money under the federal Medicaid and Medicare programs and TRICARE. Had the United States known that the Medtronic caused procurement of CRDM devices for unapproved uses and also caused CRDM devices to be implanted for unapproved, off-label uses, the United States would not have provided reimbursement for such implants under its Medicaid and Medicare plans and under TRICARE.

145. This course of conduct violated the False Claims Act, 31 U.S.C. §§ 3729 *et seq.*

146. The United States, unaware of the falsity of the claims, and in reliance on the accuracy thereof, made payment upon the false or fraudulent claims and was therefore damaged.

/ / /

COUNT FOUR

MEDTRONIC'S SCHEME WITH RESPECT TO OFF-LABEL BILLINGS AS CONSPIRACY TO SUBMIT FALSE CLAIMS (31 U.S.C. § 3729(a)(3))

147. Relator re-alleges and incorporate the allegations in paragraphs 1-146 as if fully set forth herein.

148. Medtronic combined, conspired, and agreed together with physicians and others to defraud the United States by knowingly causing false claims to be submitted to the United States for the purpose of having those claims paid and ultimately profiting from those false claims. Medtronic committed other overt acts set forth above in furtherance of that conspiracy, all in violation of 31 U.S.C. § 3729(a)(3), causing damage to the United States.

COUNT FIVE

FEDERAL FALSE CLAIMS ACT VIOLATIONS FOR MEDTRONIC'S FRAUDULENT PROMOTION OF CRDM DEVICES (31 U.S.C. §3729)

149. Relator re-alleges and incorporate the allegations in paragraphs 1-148 as if fully set forth herein.

150. Medtronic represented to physicians that CRDM devices were safe and effective for use in patients with minor heart failure symptoms or no symptoms. Such representations were false and fraudulent. However, relying on these false representations, physicians recommended and prescribed CRDM devices for use in patients with minor heart failure symptoms or no symptoms.

151. Medtronic representatives also improperly accessed patient medical records and information, at, e.g., "Know Your EF" events and in physicians' offices, inappropriately recommending specific patients as candidates for unnecessary care and implantation, leading to unnecessary diagnosis, treatment, and/or implantation and resulting in increased claims for reimbursement from federal health care systems.

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152. CRDM devices are extremely costly. As such, Medtronic caused the government and the states to incur unneeded and unwarranted costs to cover the use of CRDM devices in patients with minor heart failure symptoms or no symptoms.

153. This course of conduct violated the False Claims Act, 31 U.S.C. §§ 3729 *et seq.*

154. The United States, unaware of the falsity of the claims, and in reliance on the accuracy thereof, made payment upon the false or fraudulent claims and was therefore damaged.

PRAYER FOR RELIEF UNDER FEDERAL FALSE CLAIMS ACT

Relator respectfully requests this Court to enter judgment against Medtronic, as follows:

(a) That the United States be awarded damages in the amount of three times the damages sustained by the United States because of the false claims and fraud alleged within this Complaint, as the Civil False Claims Act, 31 U.S.C. §§ 3729 *et seq.* provides;

(b) That civil penalties at the maximum amount allowed by law be imposed for each and every false claim that Medtronic presented to the United States;

(c) That pre- and post-judgment interest be awarded, along with reasonable attorneys' fees, costs, and expenses which the Relator necessarily incurred in bringing and pressing this case;

(d) That the Court grant permanent injunctive relief to prevent any recurrence of violations of the False Claims Act for which redress is sought in this Complaint;

(e) That the Relator be awarded the maximum percentage of any recovery allowed to them pursuant the False Claims Act, 31 U.S.C. §3730(d)(1),(2);

(f) That this Court award such other and further relief as it deems proper.

COUNT SIX

VIOLATION OF THE ARKANSAS MEDICAID FRAUD FALSE CLAIMS ACT

155. Relator re-alleges and incorporate the allegations in paragraphs 1-154 as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Medtronic. Medtronic conducts business in the State of Arkansas. Upon information and belief, Medtronic's actions described herein occurred in the State of Arkansas as well.

156. This is a qui tam action brought by Relator and the Arkansas to recover treble damages and civil penalties under the Arkansas Medicaid Fraud False Claims Act, A.C.A. § 20-77-901 et seq.

157. The Arkansas Medicaid Fraud False Claims Act § 20-77-902 provides liability for any person who-

> Knowingly makes or causes to be made any false statement or representation of a material fact in any application for any benefit or payment under the Arkansas Medicaid program;
>
> At any time knowingly makes or causes to be made any false statement or representation of a material fact for use in determining rights to a benefit or payment;

158. In addition, A.C.A. § 20-77-902(7)(A) prohibits soliciting, accepting, or agreeing to accept any type of remuneration for the following:

> Recommending the purchase, lease, or order of any good, facility, service, or item for which payment may be made under the Arkansas Medicaid program.

159. Medtronic violated the Arkansas Medicaid Fraud False Claims Act § 20-77-902(1) (2) & (7)(A) from at least 2002 to the present by engaging in the fraudulent and illegal practices described herein.

160. Medtronic furthermore violated Arkansas Medicaid Fraud False

Claims Act § 20-77-902(1) & (2) and knowingly caused thousands of false claims to be made, used and presented to Arkansas from at least 2001 to the present by its violation of federal and state laws, including A.C.A. § 20-77-902(7)(A), the Anti-Kickback Act and Stark Act Requirements, as described herein.

161. Arkansas, by and through the Arkansas Medicaid program and other state health care programs, and unaware of Medtronic's fraudulent and illegal practices, paid the claims submitted by health care providers and third payers in connection therewith.

162. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to Arkansas is connection with Medtronic's fraudulent and illegal practices.

163. Had the Arkansas known that Medtronic was violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Medtronic's fraudulent and illegal practices.

164. As a result of Medtronic's violations of § 20-77-902(1) (2) & (7)(A), the State of Arkansas has been damaged in an amount far in excess of millions of dollars exclusive of interest.

165. Adolfo Schroeder is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to A.C.A. § 20-77-911(a) on behalf of himself and the State of Arkansas.

166. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Arkansas in the operation of its Medicaid program.

167. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Medtronic:

To the STATE OF ARKANSAS:

Three times the amount of actual damages which the State of Arkansas has sustained as a result of Medtronic's fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Medtronic caused to be presented to the State of Arkansas;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to A.C.A. § 20-77-911(a) and/or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this court deems equitable and just.

COUNT SEVEN

VIOLATION OF THE CALIFORNIA FALSE CLAIMS ACT (Cal. Gov't Code § 12650 et seq.)

168. Relator re-alleges and incorporate the allegations in paragraphs 1-167 as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Medtronic.

169. This is a qui tam action brought by Relator and the State of California to recover treble damages and civil penalties under the California False Claims Act, Cal. Gov't. Code § 12650 *et seq.*

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170. Cal. Gov't Code § 12651(a) provides liability for any person who—

> Knowingly presents, or causes to be presented, to an officer or employee of the state of any political division thereof, a false claim for payment or approval;
>
> Knowingly makes, uses, or causes to be made or used a false record of statement to get a false claim paid or approved by the state or by any political subdivision;
>
> Conspires to defraud the state or any political subdivision by getting a false claim allowed or paid by the state of by any political subdivision.
>
> Is a beneficiary of an inadvertent submission of a false claim to the state or a political subdivision, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the state or the political subdivision within a reasonable time after discovery of the false claim.

171. In addition, the payment or receipt of bribes or kickbacks is prohibited under Cal. Bus. & Prof. Code §§ 650 and 650.1, and is also specifically prohibited in treatment of Medi-Cal patients pursuant to Cal. Welf. & Inst. Code § 14107.2.

172. Medtronic violated Cal Bus. & Prof. Code §§ 650 and 650.1 and Cal. Welf. & Inst. Code § 14107.2 from at least 2002 to the present by engaging in the fraudulent and illegal practices described herein.

173. Medtronic furthermore violated Cal. Gov't Code § 12651(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of California from at least 2001 to the present by its violation of federal and state laws, including Cal. Bus. & Prof. Code §§ 650 and 650.1 and Cal. Welf. & Inst. Code § 14107.2, the Anti-Kickback Act and Stark Act Requirements, as described herein.

174. The State of California, by and through the California Medicaid program and other state health care programs, and unaware of Medtronic's fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

175. Compliance with applicable Medicare, Medi-Cal and the various other federal and state laws cited herein was implied, and upon information and belief, also an express condition of payment of claims submitted to the State of California in connection with Medtronic's fraudulent and illegal practices.

176. Had the State of California known that Medtronic was violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Medtronic's fraudulent and illegal practices.

177. As a result of Medtronic's violations of Cal. Gov't Code § 12651(a), the State of California has been damaged in an amount far in excess of millions of dollars exclusive of interest.

178. Adolfo Schroeder is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Cal. Gov't Code § 12652(c) on behalf of himself and the State of California.

179. This Court is requested to accept supplemental jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of California in the operation of its Medicaid program.

180. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Medtronic:

To the STATE OF CALIFORNIA:

Three times the amount of actual damages which the State of California has sustained as a result of Medtronic's fraudulent and illegal practices;

A civil penalty of up to $10,000 for each false claim which Medtronic presented or caused to be presented to the State of California;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to Cal. Gov't Code § 12652 and /or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT NINE

VIOLATION OF THE DELAWARE FALSE AND REPORTING CLAIMS ACT

181. Relator re-alleges and incorporate the allegations in paragraphs 1-180 as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Medtronic. Medtronic conducts business in the State of Delaware. Upon information and belief, Medtronic's actions described herein occurred in Delaware as well.

182. This is a qui tam action brought by Relator and the State of Delaware to recover treble damages and civil penalties under the Delaware Medicaid False Claims Act, 6 Del. C. § 1201 et seq.

183. 6 Del. C. § 1201 et seq. provides liability for any person who—

Knowingly presents, or causes to be presented, directly or indirectly, to an officer or employee of the Government a false or fraudulent claim for payment or approval;

Knowingly makes, uses or causes to be made or used, directly or indirectly, a false record or statement to get a false or fraudulent claim paid or approved;

Conspires to defraud the Government by getting a false or fraudulent claim allowed or paid;

/ / /

> Knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, increase or decrease an obligation to pay or transmit money or property to or from the Government.

184. Further, 31 Del. C. § 1005 provides that—

> It shall be unlawful for any person to offer or pay any remuneration (including any kickback, bribe or rebate) directly or indirectly, in cash or in kind to induce any other person . . . [t]o purchase, lease, order or arrange for or recommend purchasing, leasing or ordering any property, facility, service, or item of medical care or medical assistance for which payment may be made in whole or in part under any public assistance program.

185. Medtronic violated 6 Del. C. § 1201 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Delaware from 2001 to the present by its violation of federal and state laws, including 31 Del. C. §1005, and Anti-Kickback Act and the Stark Act Requirements, as described herein.

186. The State of Delaware, by and through the Delaware Medicaid program and other state health care programs, and unaware of Medtronic's fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

187. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Delaware in connection with Medtronic's fraudulent and illegal practices.

188. Had the State of Delaware known that Medtronic was violating the federal and state laws cited herein, it wound not have paid the claims submitted by health care providers and third party payers in connection with Medtronic's fraudulent and illegal practices.

189. As a result of Medtronic's violations of 6 Del C. § 1201(a), the State of Delaware has been damage in an amount far in excess of millions of dollars

exclusive of interest.

190. Medtronic did not, within 30 days after it first obtained information as to such violations, furnish such information to officials of the State responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and have not otherwise furnished information to the State regarding the claims for reimbursement at issue.

191. Adolfo Schroeder is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 6 Del. C. § 1203(b) on behalf of himself and the State of Delaware.

192. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Delaware in the operation of its Medicaid program.

193. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties against Medtronic:

To the STATE OF DELAWARE:

Three times the amount of actual damages which the State of Delaware has sustained as a result of Medtronic's fraudulent and illegal practices;

A civil penalty on not less then $5,500 and not more than $ 11,000 for each false claim which Medtronic caused to be presented to the State of Delaware;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to 6 Del C. § 1205,and /or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT NINE

VIOLATION OF THE DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT

194. Relator re-alleges and incorporate the allegations in paragraphs 1-193 as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Medtronic. Medtronic conducts business in the District of Columbia. Upon information and belief, Medtronic's actions described herein occurred in the District of Columbia as well.

195. This is a qui tam action brought by Relator and the District of Columbia to recover treble damages and civil penalties under the District of Columbia Procurement Reform Amendment Act, D.C. § 2-308.13 et seq.

196. D.C. Code § 2-30814(a) provides liability for any person who-

> Knowingly presents, or causes to be presented, to an officer or employee of the District a false claim for payment or approval;
>
> Knowingly makes, uses or causes to be made or used, a false record or statement to get a false claim paid or approved by the District;
>
> Conspires to defraud the District by getting a false claim allowed or paid by the District;
>
> Is the beneficiary of an inadvertent submission of a false claim to the District, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the District.

197. In addition, D.C. Code § 4-802(c) prohibits soliciting, accepting, or agreeing to accept any type of remuneration for the following:

> Referring a recipient to a particular provider of any item or service or for which payment may be made under the District of Columbia Medicaid program; or
>
> Recommending the purchase, lease, or order of any good, facility,

service, or item for which payment may be made under the District of Columbia Medicaid Program.

198. Medtronic violated D. C. Code § 4-802(c) from at least 2001 to the present by engaging in the fraudulent and illegal practices described herein.

199. Medtronic furthermore violated D. C. Code § 2-308.14(a) and knowingly caused thousands of false claims to be made, used and presented to the District of Columbia from at least 2001 to the present by its violation of federal and state laws, including D. C. Code § 4-802(c), the Anti-Kickback Act and the Stark Act, as described herein.

200. The District of Columbia, by and through the District of Columbia Medicaid program and other state health care programs, and unaware of Medtronic's fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

201. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the District of Columbia is connection with Medtronic's fraudulent and illegal practices.

202. Had the District of Columbia known that Medtronic was violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Medtronic's fraudulent and illegal practices.

203. As a result of Medtronic's violations of D.C. Code § 2-308.14(a) the District of Columbia has been damaged in an amount far in excess of millions of dollars exclusive of interest.

204. Adolfo Schroeder is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to D.C. Code § 2-308.15(b) on behalf of himself and the District of Columbia.

205. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the District of Columbia in the operation of its Medicaid program.

206. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Medtronic:

To the DISTRICT OF COLUMBIA:

Three times the amount of actual damages which the District of Columbia has sustained as a result of Medtronic's fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Medtronic caused to be presented to the District of Columbia;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to D. C. Code § 2-308.15(f) and /or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this court deems equitable and just.

COUNT ELEVEN

VIOLATION OF THE FLORIDA FALSE CLAIMS ACT

207. Relator re-alleges and incorporate the allegations in paragraphs 1-206 as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Medtronic. Medtronic conducts business in the State of Florida. Upon information and belief, Medtronic's actions described herein occurred in the State of Florida as well.

208. This is a qui tam action brought by Relator and the State of Florida to recover treble damages and civil penalties under the Florida False Claims Act, West's F.S.A. § 68.081 et seq.

209. West's F.S.A. § 68.082 provides liability for any person who-

> Knowingly presents or causes to be presented to an officer or employee of an agency a false claim for payment or approval.
>
> Knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by an agency.
>
> Conspires to submit a false claim to an agency or to deceive an agency for the purpose of getting a false or fraudulent claim allowed or paid.

210. Medtronic violated West's F.S.A. § 68.082 from at least 2001 to the present by engaging in the fraudulent and illegal practices described herein.

211. Medtronic furthermore violated West's F.S.A. § 68.082 and knowingly caused thousands of false claims to be made, used and presented to the State of Florida from at least 2001 to the present by its violation of federal and state laws, including the Anti-Kickback Act, and the Stark Act, as described herein.

212. The State of Florida, by and through the State of Florida Medicaid program and other state health care programs, and unaware of Medtronic's fraudulent and illegal practices, paid the claims submitted by health care providers and third payers in connection therewith.

213. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Florida in connection with Medtronic's fraudulent and illegal practices.

214. Had the State of Florida known that Medtronic was violating the federal and state laws cited herein, it would not have paid the claims submitted by

health care providers and third party payers in connection with Medtronic's fraudulent and illegal practices.

215. As a result of Medtronic's violations of West's F.S.A. § 68.082 the State of Florida has been damaged in an amount far in excess of millions of dollars exclusive of interest.

216. Adolfo Schroeder is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to West's F.S.A. § 68.083(2) on behalf of himself and the State of Florida.

217. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Florida in the operation of its Medicaid program.

218. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Medtronic:

To the STATE OF FLORIDA:

Three times the amount of actual damages which the State of Florida has sustained as a result of Medtronic's fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Medtronic caused to be presented to the State of Florida;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to West's F.S.A. § 68.085 and /or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this court deems equitable and just.